#### 

All participants (applicant, applicant's representative, PTO personnel):

(1) Steven D. Maki.

(2) Lisa Michaud.

(3) \_\_\_\_\_.

(4) \_\_\_\_.

Date of Interview: 26 May 2004.

Type: a) Telephonic b) Video Conference c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No. If Yes, brief description: \_\_\_\_.

Claim(s) discussed: 19-42.

Identification of prior art discussed: art of record.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

#### **Summary of Record of Interview Requirements**

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

- A complete and proper recordation of the substance of any interview should include at least the following applicable items:
- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
  - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Application No. 10/053,102

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed 103 rejection. Discussed Schwobel and the LEAP reference. Applicant's representative argued that there is no motivation for the combination since LEAP already makes plural devices. Applicant's representative emphasized differences between Schwobel's analytical device and the LEAP device. Examiner noted that claim 19 reads on folding an index card and cutting the folded index card to form plural devices. With respect to continuous, examiner noted that Schwobel suggests using a continuous sheet so as to obtain a high production rate and low production costs. As to claim 40, examiner noted that this claim, which describes "mechanically bonding", is directed to a non-elected invention (stapling)..

Examiner-Initiated Interview Summary	Application No.	Applicant(s)
	10/053,102	FOX ET AL.
	Examiner	Art Unit
	Steven D. Maki	1733
All Participants:	Status of Application:	
(1) <u>Steven D. Maki</u> .	(3)	
(2) <u>Lisa Michaud</u> .	(4)	
Date of Interview: 4 June 2004	Time:	
Type of Interview:  ☐ Telephonic ☐ Video Conference ☐ Personal (Copy given to: ☐ Applicant ☐ Applic  Exhibit Shown or Demonstrated: ☐ Yes ☐ No If Yes, provide a brief description: .	ant's representative)	
Part I.		
Rejection(s) discussed: 103		
Claims discussed: 19-42		
Prior art documents discussed: art of record		
Part II.		
SUBSTANCE OF INTERVIEW DESCRIBING THE GENE See Continuation Sheet	RAL NATURE OF WHAT WA	S DISCUSSED:
Part III.		
<ul> <li>It is not necessary for applicant to provide a separate directly resulted in the allowance of the application. The of the interview in the Notice of Allowability.</li> <li>It is not necessary for applicant to provide a separate did not result in resolution of all issues. A brief summand.</li> </ul>	e examiner will provide a writ record of the substance of the	ten summary of the substance interview, since the interview
		•
Steven o Maki		
(Examiner/SPE Signature) (Applican	t/Applicant's Representative S	ignature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed: Examiner proposed amending claim 19 to recite a step of folding a continuous sheet, a step of guiding the first and second portions respectively over and under a separator device, a step of passing a continuous deformable material through a heat source and an inserting and joining step. Applicant's representative made counterproposal - omitting the step of passing a continuous deformable material through a heat source. Examiner agreed that the proposed claim would be allowable over the prior art of record (including Winesett and Lindley which do not insert continuous filament) without the passing step. Applicant's representative faxed draft amendment to examiner on 6-4-04 (see INTERVIEW SUMMARY ATTACHMENT) to examiner. Examiner proposed modifying the draft amendment faxed 6-4-04 as follows: (1) in claim 19, change "handling" (line 10) to --handle--, insert --continuous-- before "deformable material" (line 14), insert --joined--- before "first and second portions" (line 20) and insert --folded sheet of-- before "handle-forming material" (line 20); (2) cancel claim 21, (3) amend claims 20, 22, 23, 26, 30, 32, 36, 37 and 39 to remove minor informalities / use consistent language and (4) amend figure 5 by deleting "18" and "48". Applicant's representative agreed to the proposed changes set forth in the examiner's amendment.

### INTERVIEW SUMMARY ATTACHMENT

attachment to paper dated 6-4-04

JUN. 4.2004 2:28PM

NUTTERMCCLENNENFISH

NO.467 P



#### FACSIMILE TRANSMITTAL SHEET

Today's Date: June 4, 2004

Time: 2:29 PM

Employee ID: 957

# of Pages: 9

From: Lisa J. Michaud

Direct Dial: 617-439-2550

Fax No: 617-310-9550

RECIPIENT	COMPANY	FAX No.	PHONE NO.
Examiner Maki	USPTO	(571) 273-1221	

#### COMMENTS:

Per my voicemail, attached please find Amendments to the Claims (as amended based on our conversation earlier today), as well as amendments to the specification and drawings, and 2 replacement drawing sheets. Please let me know if this is acceptable, and confirm that you will be issuing a Notice of Allowance.

Thank you very much,

Lisa Michaud

STATEMENT OF CONFIDENTIALITY

The documents included with this facsimile transmittal sheet contain information from the law firm of Nutter McClennen & Fish LLP which is confidential and/or privileged. The information is intended to be for the use of the addressee named on this transmittal sheet. If you are not the addressee, note that any disclosure, photocopying, distribution or use of the contents of this faxed information is prohibited. If you have received this facsimile in error, please notify us by telephone (collect) immediately so that we can arrange for the retrieval of the original documents at no cost to you.

IF THERE IS A PROBLEM WITH THIS TRANSMISSION, OR IF YOU DID NOT RECEIVE ALL PAGES, PLEASE CALL 617-439-2676, AS SOON AS POSSIBLE

FOR NUTTER McCLENNEN & FISH LLP USE ONLY

Client-Matter No. 101881-2

Nutter McClennen & Fish LLP . Attomeys at Law

World Trade Center West = 155 Seaport Blvd. = Boston, MA 02210-2604 = 617-439-2000 = Fax: 617-310-9000 = www.nutter.com
PAGE 1/9 \* RCVD AT 6/4/2004 2:34:26 PM [Eastern Daylight Time] \* SVR:USPTO-EFXRF-3/24 \* DNIS:2731221 \* CSID:01116173109000 \* DURATION (mm-ss):02-36

#### AMENDMENTS TO THE CLAIMS

1-18. (Cancelled).

19. (Currently Amended) A method for producing a plurality of medical test implements, comprising the steps of:

folding first and second portions of a handle-forming material toward one another; separating the first and second portions of the handle-forming material;

positioning a plurality of test elements, each having a predetermined length, between the first and portions of the handle forming material such that each test element is spaced apart from one another by a predetermined distance;

mechanically mating the first and second portions of the handle forming material to one another with the plurality of test elements disposed therebetween; and

folding a continuous sheet of handling forming material at a folding station such that first and second continuous portions converge toward each other;

guiding the first and second continuous portions, respectively, over and under a separator device:

inserting a deformable material between the first and second continuous portions of the folded sheet of handle forming material:

joining the first and second continuous portions together with the deformable material therebetween and then cutting the deformable material to form a test element:

repeating the inserting and joining steps such that a plurality of spaced apart test elements are between the joined first and second portions of the folded sheet; and

perforating, scoring, or cutting the first and second portions of the handle-forming material to form a plurality of medical test implements, each having a handle and a test element that is adapted to deform when a predetermined load is applied thereto.

20. (Previously Presented) The method of claim 19, wherein the handle-forming material is scored to form the first and second portions prior to folding the first and second portions.

- 21. (Previously Presented) The method of claim 19, wherein the plurality of test elements are formed from an elongate test element that is cut into predetermined lengths.
- 22. (Previously Presented) The method of claim 21, wherein the elongate test element is heated to a predetermined temperature for a predetermined time before the elongate test element is cut to form the plurality of test elements.
- 23. (Previously Presented) The method of claim 22, wherein the predetermined temperature and predetermined time are selected to allow for elimination of substantially all curvature of the elongate test element during the elongate test element.
- 24. (Previously Presented) The method of claim 23, wherein the predetermined temperature is in the range of about 250°F and 350°F.
- 25. (Previously Presented) The method of claim 23, wherein the predetermined time is in the range of about 20 seconds and 40 seconds.
- 26. (Previously Presented) The method of claim 19, wherein the predetermined length of each test element is in the range of about 37 millimeters to 39 millimeters.
- 27. (Previously Presented) The method of claim 19, wherein each test element has a diameter in the range of about 0.4 millimeters to 0.5 millimeters.
- 28. (Previously Presented) The method of claim 19, wherein the handle on each medical test implement has a width in the range of about 20 millimeters and 30 millimeters.
- 29. (Previously Presented) The method of claim 19, wherein the handle on each medical test implement has a length in the range of about 40 millimeters and 50 millimeters.

- 30. (Previously Presented) The method of claim 19, wherein the handle-forming member is formed from a material selected from the group consisting of cardboard, paperboard, a composite material and a plastic material.
- 31. (Previously Presented) The method of claim 30, wherein the plastic material is selected from the group consisting of polyethylene, polypropylene, nylon, and combinations thereof.
- 32. (Previously Presented) The method of claim 19, wherein the plurality of testing implements are each formed from a plastic material.
- 33. (Previously Presented) The method of claim 32, wherein the plastic material is nylon.
- 34. (Previously Presented) The method of claim 19, wherein the test element deforms when a load of approximately 10 grams is applied axially thereto.
- 35. (Previously Presented) The method of claim 19, further comprising the step of verifying whether the deformable test element deforms in response to the application of a predetermined load thereto.
- 36. (Currently Amended) The method of claim 19, further comprising the step of coating at least a portion of the handle-forming member material with an adhesive prior to the step of mechanically mating the first and second portions to one another.
- 37. (Previously Presented) The method of claim 19, wherein the step of mechanically mating the first and second portions to one another comprises heating the first and second portions.
- 38. (Previously Presented) The method of claim 37, wherein the first and second portions are heated using a heat/seal press heated to a predetermined temperature for a predetermined time and a precise amount of pressure that facilitates sealing of the first and second portions of the material.

NO.467 P.5

Serial No.: 10/053,102 Group Art Unit: 1733 Examiner: S. Maki Atty. Docket No.: 101881-2

- (Previously Presented) The method of claim 37, wherein the handle-forming member has 39, been pre-treated with a thermosensitive adhesive that is activated by the step of heating the first and second portions.
- 40, (Cancelled).
- 41, (Cancelled).
- 42. (Cancelled),

#### AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph starting at page 8, line 10 with the following amended paragraph:

Once scored, these portions 60A, 60B are caused to be folded toward each other as they pass through a folding station 70 (see FIG. 6) of the machine. The folding station 70 generally includes two wheels 72, 74 that are positioned such that as the handle-forming material 10 is fed between the wheels, the material 10 is caused to be folded lengthwise such that the ends 62, 66 64, 66 of the portions 60A, 60B of the material 10 converge toward each other as shown in FIG. 8.

#### AMENDMENTS TO THE DRAWINGS

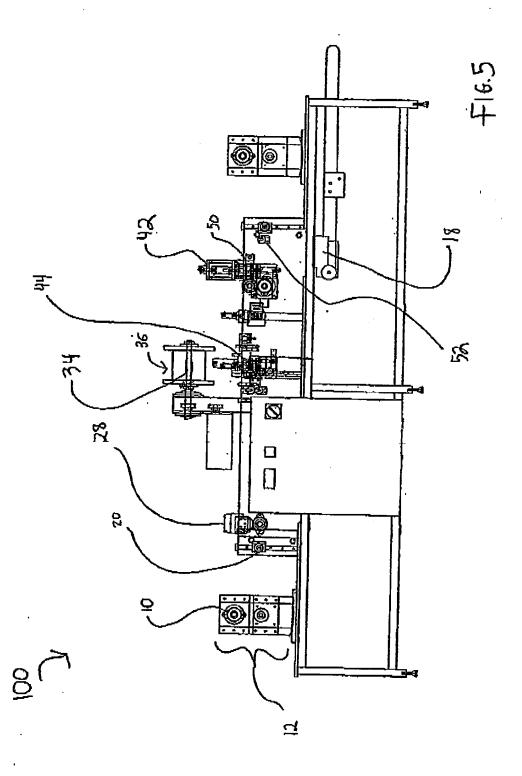
The attached replacement sheets, which includes changes to Figure 5 and Figure 8, replace the original sheets that include Figure 5 and Figure 7-9. Figure 5 is amended to remove references numbers 18 and 48, per the Examiner's request, and Figure 8 is amended to replace "62" with "64".

Attachments: Replacement Sheet (2 pages)

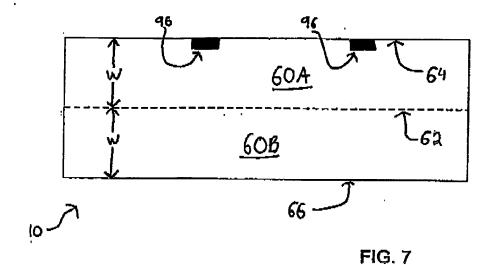
1329780.1

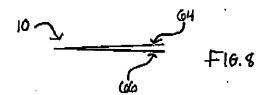
P.81881-2

## REPLACEMENT SHEET



# NUTTERMCCLENNENFISH REPLACEMENT SHEET





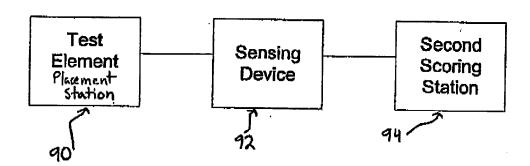


FIG. 9